

**REMARKS**

***Status of the Claims***

Claims 1, 9-12, and 20-35 are pending. Claims 1, 9-12, 20-21, and 30-35 are pending and under examination on the merits. Claims 22-29 are also pending and haven been withdrawn from consideration. Claims 1, 9-12, 20, 21, and 30-35 have been amended. Upon entry of this amendment, claims 1, 9-12, 20-35 remain pending and claims 1, 9-12, 20-21, and 30-35 will be pending and under examination.

***Summary of the Amendment***

Claim 1 has been amended to more clearly recite a composition that is effective to inhibit a Th1 T-cell immune response. Further claim 1 is amended to more clearly articulate that the composition comprises 1) a nucleic acid eukaryote cell expression carrier encoding a targeted antigen and 2) the targeted antigen that is encoded by the nucleic acid eukaryote cell expression carrier encoding a targeted antigen. Ratios of the nucleic acid eukaryote cell expression carrier to the polypeptide are stated in claim 1. Dependent claims 30-35 have been amended to maintain the language as consistent with claim 1 as amended. Support for these amendments can be found throughout the specification and the claims as-filed.

No new matter has been added.

***Brief Summary of the Invention***

The pending claims are directed to compositions that comprise 1) a nucleic acid eukaryote cell expression carrier and 2) a polypeptide and that are effective to *inhibit*, rather than enhance or induce, a Th1 T-cell immune response.

***Claim Rejections Under 35 U.S.C. § 103***

Claims 1, 9-12, 20-21, and 30-35 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Wen *et al.* (U.S. Patent No. 6,221,664) and Claims 1, 9-12, 20-21, and 30-35 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pundi (WO 02/078732).

The Office alleges that Wen discloses the structural limitations of the presently claimed invention and the inhibition of a Th2 immune response. Applicants respectfully disagree.

Wen fails to render the claims obvious because Wen fails to disclose each and every element of the claims and the Office has not provided a sufficient and articulated reason to modify Wen to yield the presently claimed invention. Accordingly, the Office has failed to establish a *prima facie* case of obviousness. The presently claimed invention is not obvious because Wen fails to disclose a composition for inhibiting a Th1 T-cell immune response comprising 1) a nucleic acid eukaryote cell expression carrier encoding a targeted antigen and 2) the targeted antigen polypeptide that is encoded by the nucleic acid eukaryote cell expression carrier encoding a targeted antigen, wherein the ratio of the nucleic acid vaccine to the antigen polypeptide is selected from the group consisting of 5:1 (w/w), from 2:1 to 10:1(w/w), from 1:5 to 5:1(w/w), and from 1:2 to 1:10(w/w); and is effective to inhibit a Th1 T-cell immune response.

The Office alleges that Wen discloses a composition that can inhibit a T-cell immune response. The Office alleges that Wen discloses a composition that increases interferon- $\gamma$  and that interferon- $\gamma$  inhibits a Th2 response (Final Office Action, citing Wen, Column 3). The Wen reference discloses that its compositions can increase interferon- $\gamma$ , but Applicants have failed to identify any place in Wen that discloses any effect on a Th2 response. Applicants respectfully request that if the objection is maintained that the Office provide a reference supporting the contention that the Th2 response is inhibited or submit a declaration attesting to the fact. However, solely in order to further prosecution, Applicants have amended the claims to recite that the composition is for inhibiting a Th1 T-cell immune response and that the composition is effective to inhibit a Th1 T-cell immune response. Wen fails to disclose a composition that is effective to inhibit a Th1 T-cell immune response.

It is well settled to establish a *prima facie* case, a reference or combination of references must disclose each and every limitation of the claim. Wen fails disclose each and every limitation. Wen does not disclose the ratios disclosed in the claims. Wen fails to disclose a composition that is effective to inhibit a Th1 T-cell immune response. The Office has failed to

properly identify the source of these elements other than unsupported statements. Accordingly, the claims are not obvious in view of Wen because the Office has failed to properly support a *prima facie* obviousness rejection.

Furthermore, the claims are also not obvious because Wen teaches away from a composition that is effective to inhibit a Th1 T-cell immune response. As set forth in the language of claim 1, the presently claimed composition is effective to inhibit a Th1 T-cell immune response. In contrast, Wen discloses compositions that are allegedly effective to enhance or induce an immune response, including a Th1 response, which is the opposite of the presently claimed compositions. A reference teaches away when one of skill in the art after reading the reference “would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path” disclosed in the reference. *In re Gurley* 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 2004). Explaining further the court stated, “a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.” *Id.* Wen teaches away because one of skill in the art reading the reference would not believe that the pending compositions would be likely to be effective to inhibit a Th1 T-cell immune response since the purpose of Wen is to enhance an immune response, which would include enhancing a Th1 T-cell immune response.

Accordingly, the presently claimed invention is not obvious in view of Wen because Wen fails to yield the presently claimed invention and because Wen teaches away. In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 103 in view of Wen be withdrawn.

Claims 1, 9-12, 20-21, and 30-35 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pundi (WO 02/078732). The Office alleges that Pundi discloses the structural limitations of the presently claimed invention and the inhibition of a Th2 immune response. Applicants respectfully disagree.

Pundi fails to render the claims obvious because Pundi fails to disclose each and every element of the claims and the Office has not provided a sufficient and articulated reason to modify Pundi to yield the presently claimed invention. Accordingly, the Office has failed to establish a *prima facie* case of obviousness. The presently claimed invention is not obvious because Pundi fails to disclose a composition for inhibiting a Th1 T-cell immune response comprising 1) a nucleic acid eukaryote cell expression carrier encoding a targeted antigen and 2) the targeted antigen polypeptide that is encoded by the nucleic acid eukaryote cell expression carrier encoding a targeted antigen, wherein the ratio of the nucleic acid vaccine to the antigen polypeptide is selected from the group consisting of 5:1 (w/w), from 2:1 to 10:1(w/w), from 1:5 to 5:1(w/w), and from 1:2 to 1:10(w/w); and is effective to inhibit a Th1 T-cell immune response.

The Office alleges that Pundi discloses a composition that can inhibit a T-cell immune response. The Office alleges that Pundi discloses a composition that increases interferon- $\gamma$  and that interferon- $\gamma$  inhibits a Th2 response (Final Office Action, page 8). Applicants have failed to identify any place in Pundi that discloses any effect on a Th1 or Th2 response. Applicants respectfully request that if the objection is maintained that the Office provide a reference supporting the contention that the Th2 response is inhibited or submit a declaration attesting to the fact. However, solely in order to further prosecution, Applicants have amended the claims to recite that the composition is for inhibiting a Th1 T-cell immune response and that the composition is effective to inhibit a Th1 T-cell immune response. Pundi fails to disclose a composition that is effective to inhibit a Th1 T-cell immune response.

It is well settled to establish a *prima facie* case, a reference or combination of references must disclose each and every limitation of the claim. Pundi fails to disclose each and every limitation. Pundi does not disclose the ratios disclosed in the claims. Pundi fails to disclose a composition that is effective to inhibit a Th1 T-cell immune response. The Office has failed to properly identify the source of these elements other than unsupported statements. Accordingly, the claims are not obvious in view of Pundi because the Office has failed to properly support a *prima facie* obviousness rejection.

Furthermore, the claims are also not obvious because Pundi teaches away from a composition that is effective to inhibit a Th1 T-cell immune response. As set forth in the language of claim 1, the presently claimed composition is effective to inhibit a Th1 T-cell immune response. In contrast, Pundi discloses compositions that are allegedly effective to enhance or induce an immune response, including a Th1 response, which is the opposite of the presently claimed compositions. A reference teaches away when one of skill in the art after reading the reference “would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path” disclosed in the reference. *In re Gurley* 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 2004). Explaining further the court stated, “a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.” *Id.* Pundi teaches away because one of skill in the art reading the reference would not believe that the pending compositions would be likely to be effective to inhibit a Th1 T-cell immune response since the purpose of Pundi is to enhance an immune response, which would include enhancing a Th1 T-cell immune response.

Accordingly, the presently claimed invention is not obvious in view of Pundi because Pundi fails to yield the presently claimed invention and because Pundi teaches away. In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 103 in view of Pundi be withdrawn.

### ***Double Patenting***

Claims 1-6, 10-12, 20, 30-35 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 10, and 11 of co-pending application No. 11/644,435. The Office alleges that although the claims are not identical they are not patentably distinct from each other because the claims of co-pending application number 11/644,435 are drawn to a composition comprising a eukaryotic cell expression vector containing nucleotide sequences encoding an allergenic protein and the protein or polypeptide that comprises an antigenic epitope of said protein. The Office alleges that the

vector comprises an RSV, CMV, or SV40 promoter and the vector is in the proportion to the protein in a ratio of 1:15 to 5:1. Applicants respectfully assert that the present obviousness-type double patenting rejection should be withdrawn since the all other rejections have been obviated and this is the only remaining rejection. The present application is the earlier filed application. Accordingly, the provisional rejection should be withdrawn and the present application should be allowed to issue.

In view of the foregoing, Applicants respectfully request that the rejection under obviousness-type double patenting be withdrawn.

***Conclusion***

Claims 1, 9-12, 20-21, and 30-35 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7820 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

/Daniel M. Scolnick, Reg. No. 52,201/  
Daniel M. Scolnick, Ph.D.  
Registration No. 52,201

Dated: **October 28, 2009**  
PEPPER HAMILTON, LLP  
400 Berwyn Park  
899 Cassatt Road  
Berwyn, PA 19312-1183  
Telephone: 610-640-7820  
Facsimile: 610-640-7835